IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 10/790,618

Applicant: van der Steen et al.

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Examiner: Brian Scott Szmal

Docket No.: 254457

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Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO OFFICE ACTION

Sir:

In reply to the Office Action dated March 16, 2006, please enter the following amendments and consider the following remarks.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

MAILING/TRANSMISSION CERTIFICATE UNDER 37 CFR 1.8 OR 1.10			
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AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions, and listings, of claims in the application.

1. (Currently amended) A method for generating hardness information of tissue subject to a varying pressure, the method comprising:

receiving signals from a tissue with a sensor for measuring the deformation of the tissue in a measuring plane defined by the sensor, which sensor, during a varying pressure exerted on the tissue, is moved along the tissue in a direction transverse to the measuring plane during the receiving signals step;

identifying strain of the tissue from the ~~resulting~~ signals received by the sensor moved along the tissue in the direction transverse to the measuring plane; and

relating the strain to at least one of either~~elasticity, hardness or~~ hardness ~~and~~or elasticity parameters of the tissue.

2. (Currently amended) The method according to claim 1, wherein the method comprises:

correlating signals consecutive over time, which signals are representative of the deformation of the tissue in case of positions of the sensor mutually moved with respect to each other; and

calculating, by means of said ~~correlation~~correlating signals step, strain in a tissue surface or tissue volume part extending practically parallel to the direction of motion of the sensor.

3. (Previously Presented) The method according to claim 1, wherein the method comprises the step of displaying elasticity and/or hardness parameters of a tissue surface or tissue volume part.

4. (Previously Presented) The method according to claim 1, wherein the signals are echographic data detected with an acoustic sensor.

5. (Previously Presented) The method according to claim 1, wherein the signals are optical data detected with an optical sensor.

6. (Previously Presented) The method according to claim 1, wherein the method comprises displaying elasticity and/or hardness parameters of the tissue with position information of the sensor and/or the tissue.

7. (Previously Presented) The method according to claim 1, wherein the signals are received during practically continuous motion of the sensor.

8. (Previously Presented) The method according to claim 1, wherein signals possessing an overlap are received.

9. (Original) The method according to claim 8, wherein an optimum overlap is determined by means of a probability function displaying the similarity between consecutive signals.

10. (Previously Presented) The method according to claim 1, wherein signals, at an assumed cyclic pressure change, are received at predetermined time intervals in the period of the motion.

11. (Previously Presented) The method according to claim 1, wherein the signals come from a blood vessel wall and the data are received only during a specific time interval of the period of the heartbeat.

12. (Previously Presented) The method according to claim 1, wherein the tissue is an artery moving through the heartbeat in the longitudinal direction, and the sensor is moved practically parallel to this direction, so that, during at least one detection period, the sensor has a practically fixed position relative to the wall of the artery.

13. (Currently amended) An apparatus for generating hardness information of tissue subject to a varying pressure, wherein the apparatus comprises:

a sensor movable through a blood vessel or body cavity for recording signals from a tissue, wherein the sensor is controlled to acquire signals from the tissue, during a period of varying pressure exerted on the tissue, while being controllably moved along the tissue in a direction transverse to a measuring plane defined by the sensor;

a processor device for collecting and processing signals from the sensor to identify strain of the tissue and to relate the strain to elasticity and/or hardness parameters of a tissue surface or tissue volume part; and

a display device for displaying elasticity and/or hardness parameters of the tissue surface or tissue volume part.

14. (Original) The apparatus of claim 13, wherein the apparatus comprises:

correlation detection means for detecting the correlation between consecutive signals, which signals are representative of the deformation of the tissue in case of positions of the sensor mutually moved with respect to each other;

the processor device being arranged to calculate by means of said correlation a strain in a tissue surface or tissue volume part extending practically parallel to the direction of motion of the sensor.

15. (Previously Presented) The apparatus of claim 13, wherein the apparatus further comprises:

a position recording means coupled with the processor device to record sensor positions.

16. (Currently amended) The apparatus of claim 13, wherein the apparatus further comprises:

an actuator for controllably moving the sensor in the direction transverse to the measuring plane.

17. (Original) The apparatus of claim 16, wherein the actuator has an adjustable speed of motion.

18. (Previously Presented) The apparatus of claim 13, wherein the apparatus further comprises:

first activating means for activating data storage means for storing signals.

19. (Previously Presented) The apparatus of claim 13, wherein the apparatus comprises:

second activating means for activating the actuator.

20. (Previously Presented) The apparatus of claim 18, wherein the activating means can be connected with an ECG recording device to become active during a predetermined part of the heartbeat.

21. (Previously Presented) The apparatus of claim 18, wherein the activating means are connected with the correlation detection means to become active at a predetermined correlation.

22. (Previously Presented) The apparatus of claim 13, wherein the sensor is arranged in a catheter, which can be inserted into a blood vessel, the sensor recording signals under controlled pullback of the catheter.

23. (Previously Presented) The apparatus of claim 13, wherein the sensor is an acoustic sensor.

24. (Previously Presented) The apparatus of claim 13, wherein the sensor is an optical sensor.

REMARKS

The Office Action dated March 16, 2006, and the reference cited therein, have been considered. Claims 1-24 were previously pending. Claims 1-8 and 10-24 have been rejected, and claim 9 is objected to as depending from a rejected claim. No claims currently stand allowed. Applicants have amended the claims to improve their clarity. Applicants note that the prior art, directed to producing spatial information in an axial cross-section (see, Torp Figs. 2 and 4 – and associated written description) does not disclose the recited invention, directed to a method for generating a tissue image that includes "measuring the deformation of the tissue in a measuring plane defined by the sensor, *which sensor, during a varying pressure exerted on the tissue, is moved along the tissue in a direction transverse to the measuring plane*." In other words, the sensor is moved along the tissue (e.g., withdrawn from a vessel) as signals for calculating tissue elasticity/hardness are acquired. As noted in paragraphs 0054 and 0055 of Applicants' published application, such movement of the sensor resulted in a practically fixed artery wall position during a series of image frame acquisitions during a particular acquisition cycle.

Applicants request favorable reconsideration of the grounds for the rejection of the previously pending claims in view of Applicants' clarifying amendment and remarks. Please charge any fee deficiencies to Deposit Account No. 12-1216.

Applicants note the Office Action's request to file a certified copy of the priority document and have submitted such document, in response to the request, to fulfill the requirement under 35 U.S.C. Section 119(b) and thereby establish a claim of priority to NL 1018864 filed on August 31, 2001.

Summary of the Rejections in View of the Prior Art

1. Claims 1-4 and 6-8 are rejected as anticipated under 35 U.S.C. Section 102(b) in view of Torp et al. US Pat. No. 6,099,471 (the Torp '471 patent).

2. Claims 5, 10-12, and 13-24 are rejected as obvious under 35 U.S.C. Section 103(a) over the Torp '471 patent in view of Panescu et al. US Pat. No. 5,848,969 (the Panescu '969 patent).

Applicants traverse the grounds for each and every rejection for at least the reasons set forth herein below. Applicants address the specific rejections in the order they arise in the Office Action.

Summary of Applicants' Disclosed/Claimed Invention

Applicants' claimed invention is directed to a method and apparatus for generating hardness/elasticity information of tissue subject to a varying pressure as a sensor is drawn in a direction transverse to a measuring plane defined by the sensor. The exemplary embodiment discloses a three-dimensional imaging procedure/apparatus wherein an intravascular ultrasound transducer is withdrawn along a section of a blood vessel, subjected to varying pressure during a cardiac cycle, to render a three-dimensional representation of the hardness/elasticity of the vessel tissue. Moving the sensor along the tissue, in the case of a cardiac cycle, has the advantage of minimizing motion of an artery wall in particular circumstances described in paragraphs 0054 and 0055 of Applicants' published application. Thus, while moving the sensor along a vessel's length has the overall effect of providing an image of a length of a blood vessel, in the short term the movement potentially minimizes the effect of an otherwise moving artery wall during a single data acquisition period.

Applicants' Response To The Office Action's 35 U.S.C. 102(b) Rejections

Applicants traverse the rejection, in **section 3** of the Office Action, of claims 1-4 and 6-8 as anticipated by the Torp '471 patent. The Torp '471 patent is directed to generating a

strain image along a beam or two-dimensional cross-sectional slice generated from a set of beams. If anything, Torp teaches maintaining a motionless sensor during signal acquisition.

In the Torp '471 patent, an imaged area is defined by *a sensor that is not moved in a direction transverse to the measuring plane.* As shown in Figs. 2 and 4 of Torp, and the associated written description, the Torp disclosure is directed to generating image data along a beam within a single plane and no transverse motion of a sensor during acquisition is suggested or disclosed. With regard to Figs. 2 and 4, the accompanying written description contains multiple references to radial "beams" and neighboring beams in a same measuring plane. Furthermore, the Torp '471 patent describes correlating signals received at different times along a same beam to determine strain. Nowhere does the Torp '471 patent even remotely suggest generating a strain image/profile through the use of a sensor that, during a time of applying a varying pressure to tissue, is moved along the tissue in a direction that is transverse to the measuring plane of the sensor. In fact, the '471 patent does not even disclose a pullback device (which would be needed to pull back the sensor in a controlled/meaningful way). Instead, the Torp '471 appears to be concerned with snapshot cross-sections (or portions thereof) without movement of the sensor along the tissue.

With specific reference to the steps recited in Applicants' claim 1, the Torp '471 patent neither discloses nor suggests a method step as recited in claim 1 (and claims 2-4 and 6-8 that depend from claim 1) wherein "which sensor, during a varying pressure exerted on the tissue, is moved along the tissue in a direction transverse to the measuring plane." Thus, in contrast to the cited Torp '471 patent which acquires data from a *same transverse position* during acquisition of multiple sets of strain data, the recited invention requires moving the imaging sensor in a direction transverse to the plane of measurement. For at least these reasons, claims 1-4 and 6-8 are not anticipated by the Torp '471 patent.

Applicants also traverse the rejection of claim 2 for at least the reasons set forth above regarding acquiring signals in a three-dimensional space through the transverse displacement of the sensor during signal acquisition.

Applicants also traverse the rejection of claim 7 since Torp does not disclose receiving signals during practically continuous motion of the sensor.

Applicants' Response To The Office Action's 35 U.S.C. 103 Rejections

Applicants traverse the rejection, in **section 5** of the Office Action, of claims 5 and 10-12 as obvious over the Torp '471 patent in view of the Panescu '969 patent for at least the reasons set forth above with regard to claim 1. Applicants note however that Panescu does not even contemplate determining tissue stiffness or strain.

Applicants traverse the rejection, in **section 6** of the Office Action, of claims 13-24 as obvious over the Torp '471 patent in view of the Panescu '969 patent. Applicants have amended claim 13 to incorporate the disclosed feature of acquiring signal information while a varying pressure is exerted upon tissue and the sensor is moved along the tissue of interest in a direction transverse to a measuring plane defined by the sensor. In view of Applicants' previous remarks regarding independent claim 1 including similar elements, Applicants' submit that claims 13-24 are patentable over the prior art. The prior art simply does not disclose or even remotely suggest acquiring, by a sensor, signals for calculating elasticity/hardness of tissue while a varying pressure is asserted on tissue and while the sensor is moved in a direction transverse to the measuring plane.

Applicants acknowledge, with appreciation, the identification of patentable subject in claim 9 of the previously pending claims.

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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